



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 7 1997

#70

Re: IVOMEC EPRINEX Pour-On for Beef and Dairy Cattle
Docket No. 97E-0308

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

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PATENT EXENSION
AND PART 350

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,427,663 filed by Merck & Co., Inc. under 35 U.S.C. § 156. The animal drug product identified in the patent extension application is IVOMEC EPRINEX Pour-On for Beef and Dairy Cattle (), which was assigned New Animal Drug Application (NADA) No. 141-079.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990).

The NADA was approved on April 16, 1997, which makes the submission of the patent term extension application on June 12, 1997, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Mollie M. Yang
Merck & Co., Inc.
P.O. Box 2000
Rahway, NJ 07065-0907